REMARKS/ARGUMENTS

Claims 1, 6-18, 20-30, 40 and 42-59 are pending in this application, with Claims 1, 40, 43, 44, 46, 51 and 52 independent. By this Amendment, Claims 7, 15, 16, 43, 44 and 46-50 are amended for clarity only, and Claims 52-59 are added. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

As noted above, the amended claims have been amended for clarity only to obviate matters of form pointed out by the Examiner and to correct informalities, and not to overcome any prior art. No new matter is added.

New Claim 52 includes the feature of Claims 1, 7, 13, and 16. Claim 52 also recites that the encapsulating teeth engaging member covers the outer labial face. This feature is clearly supported in the originally filed specification, for example, Claims 1, 7, 13, and 16; Figures 6-10; Page 3, Lines 21-24 and Page 16, Lines 7-15. New Claims 53-59 each depend from a respective one of the independent claims and recite that the substantially rigid inner flange, the substantially rigid outer flange and the web are not user conformable or mouldable in boiling water in a domestic environment, as supported for example in the originally filed Specification at Page 17, the last paragraph beginning at line 26.

FORMAL MATTERS

Claim 47 stands objected to due to a typographical error. By this Amendment, Claim 47 has been amended to correct the error as suggested by the Examiner. Withdrawal of the objection is respectfully requested.

The Examiner rejects Claims 1, 40, 46 and 51 under 35 U.S.C. §112, first paragraph. This rejection is respectfully traversed.

The Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed. In particular, the Examiner asserts that no support has been provided for the claimed feature "not user conformable or mouldable in boiling water" as recited in the rejected claims. This assertion is respectfully traversed.

The Examiner asserts that the specification provides support that the softening point of the resin is above 100 degrees Celsius, and that since the boiling point of water can be above 100 degrees Celsius at higher pressures, that the material is able to be conformable or mouldable in boiling water. Applicant respectfully traverses, at least because a skilled artisan would readily have understood that ample support is provided in the specification for the claimed feature. In particular, the original Claim 19 recites that the base member is not user conformable or mouldable in boiling water. In addition, the specification provides clear support at Page 7, lines 21-22 of the originally-filed application by disclosing that "preferably the base member is substantially rigid at temperatures of 90 degrees Celsius – 95 degrees Celsius and is not user conformable or mouldable in boiling water.

Moreover, a person of ordinary skill in the art upon reading the specification in its entirety, and not just a sentence or two thereof, would readily have understood that the preferred embodiments are typically practiced at atmospheric pressure, and not at some hypothetical high pressure that may be provided in some specialized container that would increase the atmospheric

pressure to some higher pressure. For example, as set forth on Page 1, lines 8-11, the specification provides that this invention relates particularly, but not exclusively to an oral appliance that is a sports guard for protecting the teeth of a user in contact sports such a boxing, football, grid iron and rugby. These sports are not commonly played at atmospheric pressure.

In addition, the specification provides at Page 17, the last paragraph beginning at line 26, an example use for fitting an exemplary oral appliance. In particular, in use, the oral appliance (*e.g.,* sports guard 1) may easily be fitted in a domestic environment, by immersing the guard in boiling water which causes the EVA to soften. The base member remains rigid at this temperature. As it cools to body temperature in the mouth of the user, it hardens around the teeth and the jaw of a user, and is therefore customized to snugly fit in the mouth of a user. A skilled artisan reading the specification would readily understand a domestic environment as, for example, a home, which is typically at atmospheric pressure. Therefore, the Applicant clearly demonstrates possession of the claimed invention by providing at least this example of a base member remaining rigid in the temperature of boiling water while the EVA softens in a domestic environment. Withdrawal of the rejection is respectfully requested.

Claims 7, 15, 16, 40, 43, 44, 46 and 48-50 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In response, Applicant amends Claims 7, 15, 16, 43, 44, 46 and 48-50 to render the claims definite by providing anteceded basis for the limitations pointed out by the Examiner or by providing the specific structure requested by the Examiner previously set forth in the claims by dependence.

Regarding Claim 40, Applicant respectfully traverses the Examiner's assertion that "the base member" in line 2 of the claim does not have proper anteceded basis. Applicant notes that

the first three words of Claim 40 recite "a base member", therefore providing proper anteceded basis for "the base member" recited in the following line of Claim 40. Accordingly, all of the claims addressed by the Examiner are believed to be in proper form. Withdrawal of the rejection of the claims under 35 U.S.C. §112 is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Feldbau

Claims 1, 6-9, 20, 40, 46, 47 and 50 stand rejected under 35 U.S.C. §102(b) as being anticipated by Feldbau (U.S. Patent No. 4,350,154). This rejection is respectfully traversed for at least the reasons set forth below.

The Applicant respectfully disagrees that Feldbau either expressly or inherently teaches each feature of any one of these claims. Feldbau discloses a teeth protecting device having a rigid arcuate U-shaped channel member filled with a dimethylsiloxane dental compound. The primary purpose of the device of Feldbau is to be capable of clinging to the teeth "with sufficient intensity to retain the channel-shaped member and to retain the teeth during normal exploratory and/or corrective measures carried out by dental and/or medical practitioners" (see column 2 lines 31 – 35). For example, it is well known that oral endoscopy and orotrachael intubation may result in dental damage. By way of example a copy of an article entitled "Silicone impression putty for protection of teeth during intubation" Collard, et al., *Anaesthesia*, 2007 62(10) 1080-1 is attached.

Feldbau teaches that a recognized problem with earlier devices used to protect teeth during oral procedures was that as the teeth protectors were being pulled away from the teeth, fillings and bridgework were also pulled away from the teeth. Feldbau addresses this problem by

providing a teeth protector having an outer rigid U shaped channel filled with curable dental putty in which the outer U-shaped channel is designed to *peel away* from the inner matrix after the teeth protecting function has been served. To assist in peeling away the outer U-shaped channel can have lines of weakness or vertical slots 23. After the U-shaped member has been peeled away, the remainder of the protector may be removed from the teeth in a manner less likely to pull away fillings or the like. Claim 6 of Feldbau specifically recites a method for protecting teeth during an oral exploration and/or corrective treatment.

Thus, it may be appreciated that the device of Feldbau is not concerned with protecting the teeth from impact shock but rather from chipping or other damage caused by surgical instruments. Still further, the device of Feldbau is designed to allow for ready delaminaiton of the outer channel and the inner dental putty.

Turning now to Claim 1, the Examiner considers the matrix 22 of Feldbau teaches the teeth engaging element of Claim 1. Applicant respectfully disagrees. Claim 1 requires that the teeth engaging element *encapsulates* each channel, each channel being defined by an inner flange, an outer flange and a connecting web. The definition of encapsulate is to enclose in or as in a capsule, as readily understood by a skilled artisan. The purpose of encapsulation is to "firmly and securely mount the teeth engaging elements on the base member" - see paragraph [0015]. In other words, the teeth engaging element encloses the inner flange, the outer flange and the web.

In regards to Feldbau, although the matrix material fills the channel, it does not enclose the inner and outer flanges as claimed. Feldbau clearly teaches away from encapsulation as this would prevent the U-shaped member being removed from the matrix as shown in Figure 5

(reproduced below).

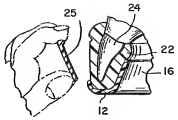

FIG. 5

Secondly, Claim 1 recites that the base member includes one or more compressible shock absorption channels which extend through a posterior outer face of the base member to a posterior inner face of the base member.

Feldbau teaches vertical slots in the outer flange so that portions can be broken away as shown in Figure 5. A slot is not a channel as claimed, nor is a slot compressible.

As Feldbau neither expressly nor implicitly teaches these features, Claim 1 cannot be anticipated. As Claims 6–9 are dependent from Claim 1, it follows that Claims 6-9 are likewise not anticipated.

With particular reference to Claim 7, this claim recites that the shock absorption channels extends from an opening in an *outer labial* face of the base member through the body thereof to an opening in an *inner lingual* face of the base member. In dental anatomy, the labial tooth is the tooth surface next to the lips and the labial surface is the surface next to the tongue. The slots 23 of Feldbau are only located on the outer labial face of the base member. The purpose of the slots 23 of Feldbau is to assist in peeling of the base from the matrix. Modifying the slots to holes extending through the body would serve absolutely no purpose at all in enabling the base to be

peeled form the matrix.

In regard to Claim 40, Claim 40 recites that the base member has pre-designated compressible sections. As discussed above, a slot is not compressible. Thus, Claim 40 is also not anticipated.

In regards to Claim 46, this claim recites compressible side openings in the outer flange. An opening is defined as "an open space in a solid matter" or an opening into an interior space, as readily understood by a skilled artisan. The slots 23 of Feldbau are *not* openings.

In regard to Claims 47 and 50, as recited these claims are dependent upon Claim 46 and thus are not anticipated.

Accordingly, none of the rejected claims are anticipated by Feldbau. Withdrawal of the rejection of the claims under 35 U.S.C. §102 is respectfully requested.

Orrico

Claims 44 and 45 stand rejected under 35 U.S.C. §102(b) as being anticipated by Orrico (U.S. Patent No. 6,170,485). This rejection is respectfully traversed for at least the reasons set forth below.

The Examiner considers that the Orrico shows a base member encapsulated by a teeth engaging element and that the base member has compressible shock absorption channels. Orrico describes an anti-snoring device designed to pull the tongue forwardly away from the air passage preventing the tongue from blocking the airway and causing snoring.

The Applicant respectfully disagrees that Orrico discloses the method of Claims 44 and 45. As discussed above, encapsulating means enclosing. Orrico simply teaches rigid trays filled with an inner mouldable portion 28. The inner mouldable portion does *not* enclose the rigid tray.

Further, the depressions 38 of Orrico are not compressible channels. The depressions 38 are formed in opposed rigid trays to define a breathing hole. The trays are described as being made of a hard or rigid plastics material. There is nothing in Orrico that discloses or even suggest that the breathing holes are compressible. Applicant submits that a person of skill in the art would have understood that a compressible breathing hole would be undesirable as it would reduce a user's ability to breath easily. This would be counter to the function of the Orica device as an anti-snoring device.

As Claim 45 is dependent upon Claim 44 it follows that Claim 45 is also not anticipated by Orrico. Withdrawal of the rejection of claims 44 and 45 under 35 U.S.C. §102 is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Feldbau

Claims 10–18, 42 and 51 stand rejected under 35 U.S.C. §103 as being unpatentable over Feldbau. This rejection is respectfully traversed for at least the reasons set forth below.

In regards to Claims 10, 11 and 12, the Examiner considers that Feldbau teaches the apparatus of Claims 1, 7-10. However, for the reasons given above, Feldbau does not teach such an apparatus. Accordingly Claims 10 and 11 must be considered patentable over Feldbau.

In regards to Claim 13, the Examiner says that Feldbau teaches in figure 2 and column 2, lines 36-45 that the teeth engaging element (22) is made of a continuous layer of material that encapsulates the base member to firmly and securely mount the layer of material on the base member. With respect, Applicant strongly disagrees with such an interpretation of Feldbau.

Figure 2 clearly shows that the base member is *not* encapsulated or enclosed by the matrix. Neither is the layer of material firmly and securely mounted to the base member. The material is able to be peeled away from the matrix as shown in figure 5. This is opposite to and teaches away from being securely and firmly mounted.

The Examiner acknowledges that Feldbau does not teach that the matrix material is thermoplastic but says that this would be an obvious design choice. Applicant respectfully disagrees, as Feldbau in fact teaches *against* a thermoplastic material as the matrix. See column 2 lines 36-40, which states that "An important aspect of this invention which distinguishes it form the aforesaid prior art is to use a matrix which will receive the impression of the teeth *without* having to elevate its temperature". This matrix is formed from a dental putty that cures in situ at room temperature.

Still further, it is submitted that a person of skill in the art would have understood from reference to figure 2 that making the matrix material 22 thermoplastic so that it softens for moulding would cause the softened matrix material to be forced into slots 23 during fitting, thereby making the guard unfit for the purpose of allowing the base to be peeled away from the cured matrix.

In regards to Claim 14, the Examiner says that Feldbau teaches in figure 2 that the continuous layer of material substantially covers the complete surface area of the base member, 12, 14, 16. However, no part of the exterior surface of base member is covered. Thus, there is no teaching to cover the complete surface area. For the reasons stated above, Feldbau teaches away from covering the exterior surface as this would prevent peeling away of the base member from the matrix.

In regards to Claim 15, the Examiner says that Feldbau teaches the apparatus of Claims 1 and 13. For the reasons given above, Applicant strongly disagrees and asserts that Claim 15 cannot be considered obvious. The Examiner also says that Feldbau in figure 2 teaches that the layer of material defines one or more openings which correspond with at least one or more channels (23). Looking at Figure 2, reproduced below for convenience, the Applicant considers that this figure clearly shows that there are no such openings in the matrix 22 as discussed in greater detail above.

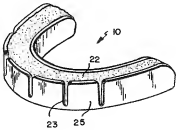

FIG.2

In regards to Claim 16, the Examiner says that Feldbau in figure 2 teaches that the layer of material 22 extends across and covers the one or more openings and closes of the interior space defined by the channels. Applicant respectfully points out that the material 22 cannot both cover an opening and expose the same opening. In any case, as Feldbau does not teach the apparatus of Claims 1 and 13, Claim 16 cannot be considered to be obvious.

In regards to Claims 17 and 18, as the apparatus of Claims 1 and 13 are not taught by Feldbau, then the Claims 17 and 18 cannot be considered to be obvious. In regards to Claim 42, as Feldbau does not teach the apparatus of Claim 40 as discussed above, and thus Claim 42 cannot be considered to be obvious.

In regards to Claim 51, the Examiner says that Feldbau in figure 2 teaches a substantially

rigid plastic base member that has a teeth engaging element encapsulating each channel. Applicant reiterates comments made above that encapsulate means to enclose. The teeth engaging element 22 may fill the channel, but it does not enclose the channel. Accordingly Claim 51 cannot be considered obvious over Feldbau. Withdrawal of the rejection of Claims 10-18, 42 and 51 under 35 U.S.C. §103 is respectfully requested.

Feldbau and Kittelsen

Claims 21-25, 28-30 and 43 stand rejected under 35 U.S.C. §103 as being unpatentable over Feldbau in view of Kittelsen, et al. (U.S. Patent No. 6,691,710). This rejection is respectfully traversed.

In regards to Claims 21-25 and 28-30 as Feldbau does not teach the apparatus of Claim 1, and Kittelsen does not teach the claimed features missing in Feldbau as discussed above, then these claims cannot be considered obvious. In regards to Claim 43, as Feldbau does not teach the apparatus of Claim 40, and Kittelsen does not teach the claimed features missing in Feldbau as discussed above, then Claim 43 cannot be considered obvious. Withdrawal of the rejection to Claims 21-25, 28-30 and 43 under 35 U.S.C. §103 is respectfully requested.

Feldbau and Adell

Claims 26, 48 and 49 stand rejected under 35 U.S.C. §103 as being unpatentable over Feldbau in view of Adell (U.S. Patent No. 4,955,393). This rejection is respectfully traversed for at least the reasons set forth below.

In regards to Claim 26, as Feldbau does not teach the apparatus of Claim 1, Claim 26 cannot be considered obvious. Further, Claim 26 recites an appliance having upper and lower channels for receiving upper and lower rows of teeth. The Examiner considers that it would

have been obvious to modify the apparatus of Feldbau to cover upper and lower rows of teeth as this is taught by Adell. The Applicant disagrees.

The apparatus of Adell is a double arch guard that receives upper and lower rows of teeth in a clenched conformation. The guard of Feldbau is designed to protect the teeth during oral procedures. In such procedures it is necessary for the patient's mouth to be open so that the dentist or medical practitioner can access the space between the upper and lower rows of teeth or to intubate the patient. Such access would be impossible with the double arch mouthguard of Adell. Consequently, modifying the guard of Feldbau as taught by Adell would make the guard unfit for its purpose. This may clearly be seen by reference to the photograph on the attached article in Exhibit I. Thus such a modification cannot be considered obvious.

In regards to Claims 48 and 49, as Feldbau does not teach the apparatus of Claims 46 and 47 Claims 48 and 49 cannot be considered to be obvious. The Examiner says that it would have been obvious to modify the outer flange taught by Feldbau as this element is known to enable the deviee of Feldbau to correspond to both the upper and lower dental arches. However, as discussed above, such a modification would make the guard of Feldbau unfit for its intended purpose. Therefore, again, Adell teaches away from the proposed combination. Withdrawal of the rejection of Claims 26, 48 and 49 under 35 U.S.C. §103 is respectfully requested.

Feldbau, Kittelsen and Hayes

Claim 27 has been rejected under 35 U.S.C. §103 as being unpatentable over Feldbau in view of Kittelsen and further in view of Hayes (U.S. Patent No. 5,092,346). This rejection is respectfully traversed for at least the reasons set forth below.

The Examiner asserts that Hayes teaches the features of Claim 27 missing in Feldbau and

Kittelsen. However, Feldbau and Kittelsen do not teach the features of Claim 1, from which Claim 27 depends. Hayes also does not teach the missing features, and thus a combination of the references still would not have arrived at the subject matter of Claim 1 or of Claim 27. Withdrawal of the rejection of Claim 27 under 35 U.S.C. §103 is respectfully requested.

CONCLUSION

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below to expedite prosecution of the application.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
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March 8, 2011

By _____
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Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.

CERTIFICATE OF MAILING/TRANSMISSION PURSUANT TO 37 CFR 1.8

I hereby certify that this correspondence and any attachments referenced therein is/are being mailed/transmitted to the USPTO by: (A) first class U.S. mail with sufficient postage (37 CFR § 1.1(a)); (B) facsimile (37 CFR § 1.6 (d)); or (C) EFS-Web (37 CFR § 1.6(a)(4)) on the date shown below.

Date: March 8, 2011 Signature: _____

Name: Michael J. Cornelison

EXHIBIT I

incidence in PDPH [1, 2]. We removed these needles and our audit the following year (2006) demonstrated that there had been no cases of PDPH after 143 spinal anaesthetics.

It needs extremely good eyesight to spot the difference between the tips of these two spinal needles, whereas checking the packaging would have revealed the difference immediately. It is worth noting that the reference code for the lancet point needle is 100/496/025 and that for the pencil point needle is 100/496/125. We presume that an error had been made when the needles were being ordered which resulted in a batch of lancet point needles being delivered and used.

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Venocaval compression due to abdominal post support and positioning during orthopaedic anaesthesia

An elderly male patient required a revision of his total hip replacement. He was hypertensive, on bisoprolol 2.5 mg once daily. His blood pressure was well controlled and he had a good exercise tolerance for his age. A preoperative ECG showed old left bundle branch block, and blood test results were within normal limits. He received a combined spinal and general anaesthetic. The spinal block was performed with the patient in the sitting position using 2.5 ml of 0.5% hyperbaric bupivacaine and diamorphine 300 μg. The block was present at T8 bilaterally. General anaesthesia was induced with propofol, a laryngeal mask airway was inserted, and anaesthesia was maintained with remifentanil, oxygen, air and desflurane. The patient was stable initially on the operating table in the right lateral position. An abdominal post support was applied, following which he suddenly became hypotensive. Ephedrine was given in incremental doses up to 30 mg, and there was little response in blood pressure with the systolic blood pressure remaining at about 60 mmHg. Metaraminol and a colloid infusion were then used to maintain the systolic pressure at 90–100 mmHg. The surgeons complained of venous oozing in spite of his low blood pressure, and the estimated blood loss was ~2.5 l. At the end of the operation the abdominal post support was removed and the patient's blood pressure immediately returned to the pre-operative level. He recovered well and was discharged without any complications.

We conclude that this case was an example of venocaval compression due to positioning and application of an abdominal post support. Anaesthetists who conduct orthopaedic anaesthesia should be aware of this potential complication.

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Silicone impression putty for protection of teeth during intubation

It is well known that there is a significant risk of damage to the upper anterior teeth during tracheal intubation. Indeed, dental injury is the most common complaint against anaesthesia providers [1, 2]. The left maxillary central incisor is at most risk of damage (51%). Tooth damage is five times more likely when there is pre-existing dental pathology such as caries, periodontal disease, restorations and chipped, cracked, or brittle teeth [1, 2]. As a result, there are numerous remedies in the literature including additional taping on the laryngoscope, or the preoperative fabrication of a custom-made tooth guard. These techniques can reduce the risk of damage to teeth but their disadvantage is their inconvenience.

Our technique is simple and quick and requires no prior planning or expertise. Dental silicone impression putty (for example President Putty, Claudius Ash, Potters Bar, UK, or Aquasil, Dentsply Ltd, Plymouth, UK) is mixed and placed around the maxillary anterior teeth (Fig. 3). It reduces the risk of enamel fracture or chipping by directly shielding the teeth and prevents the avulsion of teeth by splinting them together, thereby providing increased anchorage. This material is readily available and there is no special technique to its use; equal portions of the base and catalyst are mixed by hand

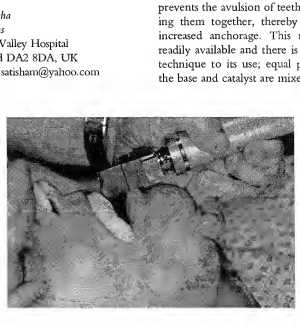

Figure 3 Silicone impression putty protecting the anterior maxillary teeth.

until a uniform colour is achieved (latex gloves should be removed for mixing), usually in about 45 s. A sausage-shaped mass is created and this is moulded around the front teeth. It will set in approximately 5 min. The putty can be kept in theatre and mixed just before intubation.

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A monitor to facilitate use of the Airtraq® laryngoscope

We read with interest the series of Maharaj et al. which described the benefits of the Airtraq® laryngoscope (Prodol Meditec S.A., Vizcaya, Spain) as a rescue airway device following direct laryngoscopy [1]. Increasing evidence indicates the emerging role of this new videolaryngoscope for both routine and difficult airway management [2–4]. One limitation is that only the airway operator can view the image of the glottis through the viewfinder. The Airtraq camera, which is an optional accessory that can be purchased from the manufacturer, can be used to transmit the images to an external monitor. This system is useful for training or teaching purposes or when it is helpful to have other physicians watch the intubation process. There are, however, some technical difficulties in manipulating the laryngoscope while viewing the events on a separate monitor placed at the side of the patient. We have introduced a monitor that can be attached to the top of the Airtraq. The Movie Vision® S (System Talks Inc., Tokyo, Japan) is a multimedia system that includes a built-in 6.4 cm LCD display and sufficient memory to store the video image. This small device, weighing 95 g, can be attached to the top of the Airtraq camera with a hook-and-loop fastener (Fig. 4). The arrangement allows the laryngoscopist to focus on the monitor screen, the laryngoscope and the patient's face all at once and makes the manipulation of the device easier.

Figure 4 The Movie Vision S monitor attached to the top of the Airtraq laryngoscope.

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